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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,269	12/21/2001	Steven Craig Gehling	17,117	3066

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EXAMINER

STEPHENS, JACQUELINE F

ART UNIT PAPER NUMBER

3761

DATE MAILED: 03/03/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,269

Applicant(s)

GEHLING ET AL.

Examiner

Jacqueline F Stephens

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,48,55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,48,55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> |

Continuation of Attachment(s) 6). Other: Marked up copy of Figure 3 of USPN 5273521.

DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims 35, 48, 55, and 56 is withdrawn in view of the newly discovered reference(s) to Munro USPN 2110962 and in view of Peiler et al. USPN 5273521.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Peiler et al. USPN 5273521.

As to claim 35, Peiler discloses an absorbent device **10** adapted to deliver a therapeutic agent to a user, the device comprising:

a body **12** having a proximal end and a distal end and adapted to be positioned entirely within the user, the body including

an absorbency zone (examiner has designated as **AZ**, Figure 3) adjacent the distal end, wherein the absorbency zone includes absorbent material (col. 2, lines 44-45);

an application zone (examiner has designated as **APZ**, Figure 3) adjacent the proximal end and spaced apart from the distal end, wherein the application zone has a surface **24**; and

a formulation including a therapeutic agent **20** positioned substantially adjacent the surface within the application zone (col. 2, lines 38-39), wherein the formulation including a therapeutic agent includes a hydrogel material or a foam component (col. 2, lines 2-4).

4. Claims 48 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Munro USPN 2110962.

As to claim 48, Munro discloses a method for producing a device for delivering a therapeutic agent to a user, the method comprising:

manufacturing a tampon (page 1, col. 1, lines 1-5) having a body with a distal end **1/2/3**, a proximal end **4** (Figure 6), an absorbency zone adjacent the distal end (Figure 6, absorbent material **6**), and an application zone (areas **1** and **3**) adjacent the proximal end, wherein the body is adapted to be positioned entirely within the user (page 1, col. 1, lines 22-41; page 3, col. 2, lines 15-17), wherein the application zone has a surface, which is the outer or inner surface of the body at the application zone areas **1** and **3**. Munro discloses the body of the form in Figure 6 may be a wholly

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soluble form, which is manufactured of a material such as gelatin, glycerin or like substances, with the absorbent material sealed therein. Munro further discloses a medicament or drug may be mixed into the body of glycerine or gelatin (page 3, col. 2, lines 1-27). Therefore, Munro satisfies the limitation of locating a formulation including a therapeutic agent substantially adjacent the surface within the application zone, including applying the formulation including a therapeutic agent to the material before the body is manufactured.

As to claim 55, Munro discloses an absorbent device (Figure 3) adapted to deliver a therapeutic agent to a user, the device comprising:

- a body having a proximal end (head portion 1) and a distal end (cylindrical portion 4), the body including

- an absorbency zone (area 4) adjacent the distal end, wherein the absorbency zone includes absorbent material (see Figure 3 page 3, col. 2, lines 8-11);

- an application zone adjacent the proximal end and spaced apart from the distal end, wherein the application zone has a surface 2; and wherein the application zone consists essentially of nonabsorbent material – Munro discloses the application zone (head portion) in Figure 3 can be made of insoluble material such as rubber or aluminum (page 3, col. 1, lines 30-56);

a formulation including a therapeutic agent positioned substantially adjacent the surface within the application zone (page 2, col. 2, line 75 through col. 2, line 15; page 3, col. 2, lines 57-63).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Munro
USPN 2110962.

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As to claim 56, Munro discloses the method for making for producing a device for delivering a therapeutic agent the method comprising: manufacturing a tampon having a body with a distal end (head portion 1), a proximal end (cylindrical portion 4), an absorbency zone adjacent the distal end (see Figures 3 and 6), and an application zone adjacent the proximal end (see Figure 7), wherein the application zone has a surface 2.

Munro does not specifically disclose the therapeutic agent is located adjacent the surface after the body is compressed. However, Munro discloses portions of the article may be compressible (page 2, col. 1, lines 20-27). Munro further teaches the body may be molded to desired form (page 2, col. 1, lines 30-34) and in suitable shapes to treat the cervix, cervical canal, and uterus (page 2, col. 1, lines 69-74). Based on the teachings of Munro, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body to be compressed in order to achieve a desired shape to conform to the vaginal area or to have an appropriate shape for a specific use. Munro further teaches inserting medicaments into the body or on the surface of the body (page 2, col. 2, line 75 through col. 2, line 15; page 3, col. 2, lines 57-63).


Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Allaire et al. USPN 544499 is cited to show an absorbent device to be inserted into the body that is provided with a hydrogel material. Pacini USPN 3393678 is cited to show a tampon with a medicament on its surface.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F Stephens whose telephone number is (703) 308-8320. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703)305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacqueline F Stephens 
Examiner
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February 28, 2004